Docket: 2874 (203-3510)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Scott Cunningham	**Examiner:**	Jonathan A. Hollm
Serial No.:	10/677,208	**Group:**	3734
Filed:	October 2, 2003	**Conf. No.:**	9627
For:	**SHARPOINT NEEDLE**	**Dated:**	November 12, 2010

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Va. 22313-1450

Filed Via EFS-Web

BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action mailed on May 27, 2010 and an Advisory Action mailed on July 30, 2010 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20(b)(2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 555 Long Wharf Drive, New Haven, CT 06511.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: November 12, 2010

Tricia Tucci

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and/or the assignee of Appellant's interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

The status of the claims of this application is as follows:

A) Claims 2, 3, 10, 11, 13, 14, 16-20, and 22-25 are pending, stand finally rejected, and are being appealed; and

B) Claims 1, 4-9, 12, 15, and 21 have been canceled.

An accurate copy of claims 2, 3, 10, 11, 13, 14, 16-20, and 22-25 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments to the claims were submitted after the Final Office Action of May 27, 2010. The Advisory Action mailed on July 30, 2010 indicated that the request for consideration had been considered but did not place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 20 is directed to a surgical needle including an elongated needle body defining a longitudinal axis and proximal and distal ends. (*See, e.g.,* Specification page 6, lines 13-15 and Figures 1-3). The elongated needle body includes a main shaft adjacent the proximal end, a needle end adjacent the main shaft defining a generally diamond-shape in cross-section along an axis transverse to the longitudinal axis and a maximum cross-sectional dimension greater than a corresponding maximum cross-sectional dimension of the main shaft, and a needle tip extending distally from the needle end defining a generally diamond-shape in cross-section along an axis transverse to the longitudinal axis and having an extreme needle point. (*See, e.g.,* Specification page 6, lines 10-12; page 7, lines 13-22; page 8, lines 2-9; and Figures 3, 5, and 6). The needle end includes a first distinct set of four generally concave intersecting surfaces extending between the needle tip and the main shaft and the needle tip includes a second distinct set of four generally concave intersecting surfaces extending between the needle point and the needle end to intersect the first set of concave surfaces of the needle end. (*See, e.g.,* Specification page 7, lines 15-19; page 8, lines 2-5; and Figures 3 and 11). Cutting edges are disposed along each respective line of intersection of the first set of four surfaces of the needle end with the second set of four surfaces of the needle tip. (*See, e.g.,* Specification page 8, lines 11-14).

Independent claim 23 is directed to a surgical needle including an elongated needle body defining a longitudinal axis and proximal and distal ends. (*See, e.g.,* Specification page 6, lines 13-15 and Figures 1-3). The elongated needle body includes a main shaft adjacent the proximal end, a first distinct set of at least three non-linear intersecting surfaces distally

extending from the main shaft, and a second distinct set of at least three non-linear intersecting surfaces contiguous with the first set of at least three non-linear intersecting surfaces and extending distally therefrom to an extreme distal needle point. (*See, e.g.*, Specification page 3, line 20 to page 4, line 4). The at least three non-linear intersecting surfaces of the first set and the at least three non-linear intersecting surfaces of the second set define respective cutting edges along each line of intersection of the first distinct set of at least three non-linear intersection surfaces with the second distinct set of at least three non-linear intersecting surfaces. (*See, e.g.*, Specification page 4, lines 4-9).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant requests review of the following outstanding grounds of rejection:

A) The rejection of claims 2, 3, 10, 11, 20, and 22 under 35 U.S.C. §103(a) over U.S. Patent No. 4,513,747 to Smith et al. (hereinafter, "Smith") in view of U.S. Patent No. 5,464,422 to Silverman (hereinafter, "Silverman"), U.S. Patent No. 20,409 to Cottrill (hereinafter, "Cottrill"), and U.S. Patent No. 5,403,344 to Allen (hereinafter, "Allen"); and

B) The rejection of claims 13, 14, 16-19, and 23-25 under 35 U.S.C. § 103(a) over Smith in view of Silverman and Cottrill.

VII. ARGUMENTS

A. Claims 2, 3, 10, 11, 20, and 22 are patentable under 35 U.S.C. §103(a) over Smith in view of Silverman, Cottrill, and Allen

In rejecting the present claims under 35 U.S.C. §103(a), the Examiner has failed to establish that the references render obvious the pending claims. As discussed in detail below, Smith, Silverman, Cottrill, and Allen simply fail to provide any basis for concluding that the specifically recited elements should be combined to form the claimed surgical needle. Thus, the Examiner has failed to set forth a *prima facie* case of obviousness and the rejection of independent claim 20, and claims 2, 3, 10, 11, and 22 which depend therefrom should be reversed.

Independent claim 20 is directed to a surgical needle including, *inter alia*, an elongated needle body defining a longitudinal axis and including a main shaft, a needle end adjacent the main shaft defining a generally diamond-shape in cross-section along an axis transverse to the longitudinal axis, and a needle tip extending distally from the needle end defining a generally diamond-shape in cross-section along an axis transverse to the longitudinal axis. The needle end includes a first distinct set of four generally concave intersecting surfaces extending between the needle tip and the main shaft and the needle tip includes a second distinct set of four generally concave intersecting surfaces extending between the needle point and the needle end to intersect the first set of concave surfaces of the needle end. Cutting edges are disposed along each respective line of intersection of the first set of four surfaces of the needle end with the second set of four surfaces of the needle tip.

Smith relates to a surgical needle having one or more cutting edges converging towards a needle tip which are formed at the intersection of a plurality of planar surfaces. As

illustrated in FIGS. 1-3 of Smith, reproduced hereinbelow, surgical needle 40 includes a cutting portion 42 including a main cutting edge 21 formed at the bottom of the cutting portion 42 by the intersection of planar surfaces 31 and 32 and secondary cutting edges 22 and 23 formed by the intersection of a third planar surface 33 (located on the top of the cutting portion 42) with planar surfaces 31 and 32, respectively.

FIG-1

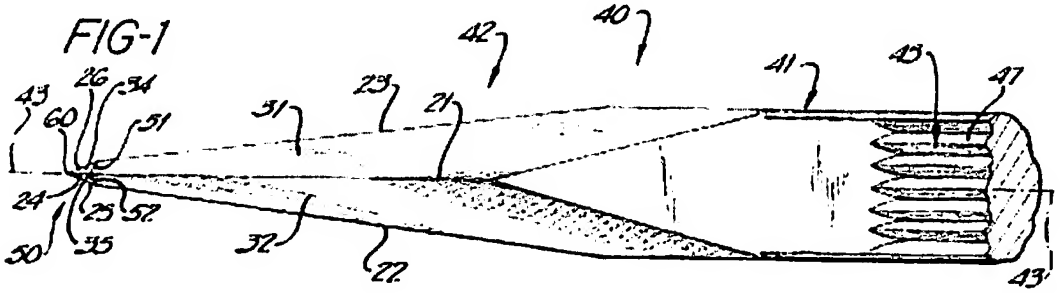


FIG-2

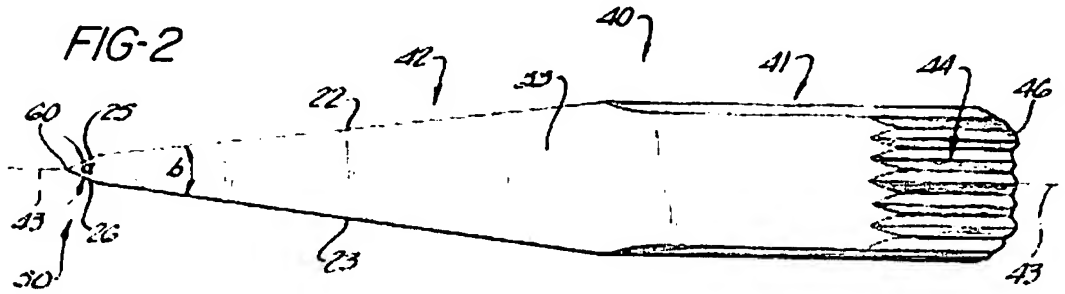
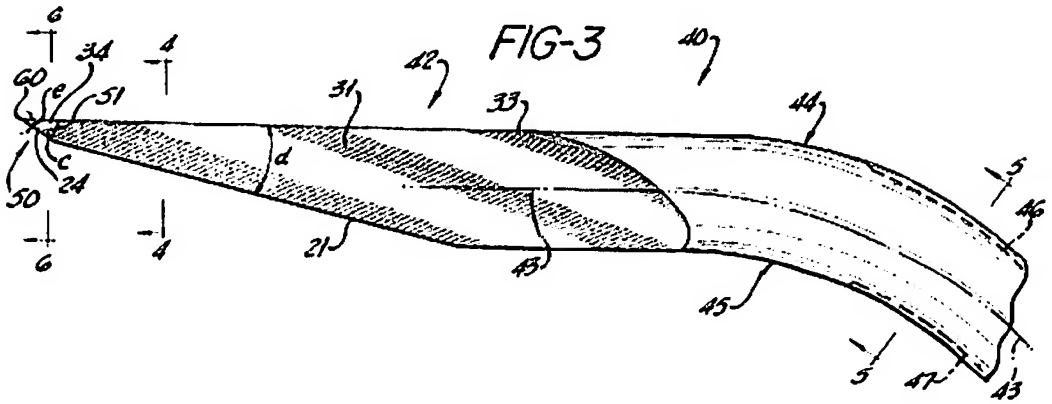


FIG-3



The cutting portion 42 includes an end portion 50 and a tip 60. Planar surfaces 34 and 35 are formed at the bottom of end portion 50 thereby creating three additional cutting edges

24, 25, and 26. "It will be noted that cutting edge 24 constitutes an extension of cutting edge 21 (FIG. 3) and said cutting edge 24 extends to the tip 60 which lies at the intersection of the reference plane and planar surface 33 (FIG. 2)." (Smith at column 4, lines 54-58). The intersection between surfaces 31 and 34 form edge 51 and the intersection between surfaces 32 and 35 to form edge 52. No edge is disposed along extended surface 33 as shown above.

Nowhere does Smith indicate edges 51 and 52 are cutting edges. When Smith discusses edges 51 and 52, he clearly refers to these "edges" with specificity. When Smith discusses edges 21, 22, 23, 24, 25, and 26, he clearly refers to these "cutting edges" with specificity. There is not express teaching or any extrinsic evidence that edges 51 and 52 are cutting edges or that edges 51 and 52 would be recognized as cutting edges by a person of ordinary skill in the art.

Even assuming, *arguendo*, that edges 51 and 52 could be cutting edges, Smith fails to disclose any edge between the intersection of the extended surface 33 as shown above. Therefore, Smith fails to disclose or suggest a surgical needle having first and second sets of surfaces with cutting edges *disposed along each respective line of intersection* of the first and second sets of surfaces as recited in claim 20.

Moreover, Smith states "[a]lthough the preferred needle of the present invention is *triple edged* with three smaller additional cutting edges located at the tip, nevertheless *the invention includes needles formed with fewer than three edges*, and in which there are at least two additional intersecting planar surfaces at the tip portion, forming one or more additional cutting edges." (Smith at column 2, lines 51-57, Emphasis added). Accordingly, Smith fails to provide any teaching or suggestion of having more than three cutting edges.

Furthermore, pages 3-4 of the Final Office Action provide additional deficiencies

of Smith as follows:

> The device of Smith is not explicitly disclosed with the first and second sets having four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section and means for attaching a suture.... The modified device of Smith in view of Silverman is not explicitly disclosed with the first and second sets being generally concave.... The modified device of Smith in view of Silverman et al and Cottrill is not explicitly disclosed with the needle end having a maximum cross-section dimension greater than a maximum cross-sectional dimension of the main shaft.

In an attempt to cure a portion of the deficiencies of Smith, the Examiner relies on Silverman asserting that Silverman discloses a needle having four sides symmetrically arranged about a longitudinal axis to form a diamond cross-section, and alleging that it would have been obvious to a person having ordinary skill in the art to modify the device of Smith "to have the first and second sets have four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section... in order to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue."

The burden of establishing a prima facie case of obviousness falls on the Examiner. Ex parte *Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish a prima facie case of obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, it is not sufficient to show that all the elements exist in the prior art, since a claimed invention composed of several elements may not be proved obvious merely by demonstrating each element was known, independently, in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a

conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and must be based on objective evidence of record. *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Here, the proposed reasoning for combining the references is that one skilled in the art would have modified the device of Smith to have first and second sets having four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section in order to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue. The Examiner, however, has not pointed to any teaching in the reference that first and second sets of four sides would provide for more efficient cutting and penetration of tissue. Furthermore, Smith provides cutting edges around the circumference of the needle and thus, it is not seen where it is suggested that four edges is more efficient at cutting and penetrating tissue than three edges.

In the Advisory Action, the Examiner states that "[a]s evidence, Otsuka et al (US Patent Number 5,178,628; cited in Applicant's IDS filed 23 January 2004), discloses that a "generally square cross-section" in a needle achieves good penetrating ability (column 2, lines 16-21)." Smith, however, teaches a surgical needle for suturing through "calcified tissue, cartilage or bone." (Smith at column 1, lines 7). Thus, the needle of Smith is sufficiently sharp and achieves good penetrating ability for use on hard tissue.

Absent any teaching in one of the two applied references that more cutting edges would improve the efficiency of cutting and penetration of tissue, there is no rational underpinning to support a conclusion of obviousness.

Moreover, the combination of Smith and Silverman as suggested by the Examiner

is improper. Silverman relates to a suture needle having a shaft portion 11, a tip portion 13, a conical point portion 15, and a point 17 as illustrated in FIG. 1A of Silverman, reproduced below.

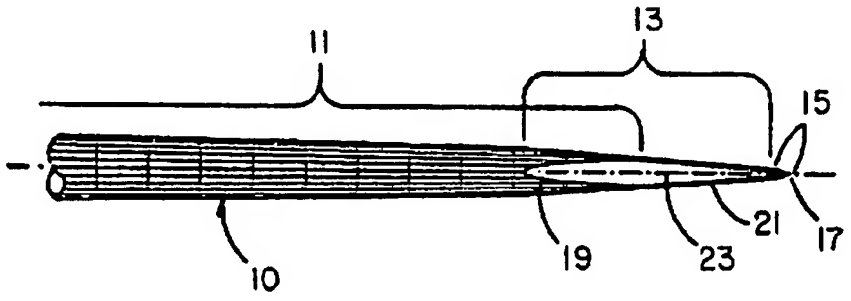


FIG. 1A

The tip portion 13 has at least two substantially flat surfaces and the conical point portion 15 has a conical shape having a substantially round cross section adjacent to the point 17 of the needle. "The conical point portion of the surgical needle of the present invention achieves a strong, burr-resistant point offering both good strength and good piercing characteristics with corresponding low penetration forces." (Silverman at column 2, lines 5-8). "Conical point portion 15 is of substantially round cross section adjacent to point 17. By substantially round cross section is meant a round or substantially rounded cross section *without any sharp, angular, or square edges*." (Silverman at column 3, lines 19-22, Emphasis added). Accordingly, Silverman effectively teaches away from having cutting edges on the portion of the needle that is proximal to the needle point and thus, fails to provide any motivation to combine the two pieces of art. References cannot be combined where a references teaches away from their combination.

Thus, Silverman's disclosure of having a conical point portion without any sharp edges, in combination with Smith's disclosure that three or fewer cutting edges produces a sharp needle (See generally, columns 1 and 2 of Smith describing the prior art and objectives of his

invention), fail to provide any motivation whatsoever to modify the needle of Smith to include two distinct sets of four generally concave intersecting surfaces and cutting edges disposed along each respective line of intersection of the first and second sets of four surfaces.

In the Advisory Action, the Examiner states that:

> [T]he Silverman reference is being relied upon for a teaching of providing four sides symmetrically arranged about a longitudinal axis of the needle to form a diamond cross-section, not two sets of planes intersecting to form cutting edges. In the rejection, Smith discloses sets of planes intersecting to form edges and is modified with the Silverman reference to include four planes in each set of planes that are symmetrically arranged about the longitudinal axis of the needle.

The Examiner, however, has failed to provide a convincing line of reasoning as to why and how one skilled in the art would have combined a reference teaching a surgical needle with a specific three-sided geometry in which the bottom plane of the cutting portion is different than the planes on the top of the cutting portion with a reference teaching a four-sided geometry to produce the claimed surgical needle.

Obviousness is determined as a matter of foresight, not hindsight. Only Applicants' disclosure provides any suggestion to provide a surgical needle with the recited features. Where there is no rational underpinning in the references to support the Examiner's rationale for combining the references in the manner necessary to arrive at the claimed subject matter, the Examiner is clearly using Applicants' disclosure as a blueprint for piecing together the prior art to defeat patentability, which is the essence of hindsight.

Cottrill and Allen fail to cure the deficiencies of Smith and Silverman as Cottrill is relied upon for the recitation of concave surfaces in a needle and Allen is relied upon for the recitation of a needle end defining a maximum cross-sectional dimension being greater than a

maximum cross-sectional dimension of the main shaft. Cottrill and Allen do not teach or suggest any of the above-noted deficiencies of Smith and/or Silverman.

Thus, the references, alone or in combination, fail to teach or suggest the recited limitations of claim 20. Therefore claim 20 defines over Smith, Silverman, Cottrill, and Allen and the rejection of claim 20 should be reversed. For at least these reasons, among others, claims 2, 3, 10, 11, and 22, which depend from claim 20 and contain all of the features recited therein, are also allowable over Smith, Silverman, Cottrill, and Allen, and the rejection of claims 2, 3, 10, 11, and 22 should also be reversed.

B. Claims 13, 14, 16-19, and 23-25 are patentable under 35 U.S.C. §103(a) over Smith in view of Silverman and Cottrill

The Examiner has not established the essential elements for a *prima facie* case of obviousness. The references fail to disclose the various elements, do not suggest the claimed combination, and the Examiner has not presented a convincing line of reasoning for combining the references to produce the claimed surgical needle. Moreover, as stated above, the combination of Smith and Silverman is improper. As a result, these rejections should be reversed.

As the following discussion shows the Examiner has failed to show how the prior art teaches or suggests all of the features of Appellant's independent claim 23. The combination of Smith, Silverman, and Cottrill simply fails to disclose or suggest the claimed surgical needles. Accordingly, the rejection of independent claim 23, and claims 13, 14, 16-19, 24, and 25 which depend therefrom, should be reversed.

The arguments presented above with respect to claim 20 apply with equal force to

claim 23. In summary, it is the Appellant's position that the Examiner has failed to present a *prima facie* case of obviousness.

Independent claim 23 differs from claim 20 in that claim 23 recites, *inter alia*, an elongated needle body defining a longitudinal axis and including a main shaft, a first distinct set of at least three non-linear intersecting surfaces distally extending from the main shaft, and a second distinct set of at least three non-linear intersecting surfaces contiguous with the first set of at least three non-linear intersecting surfaces and extending distally therefrom to an extreme distal needle point. The at least three non-linear intersecting surfaces of the first set and the at least three non-linear intersecting surfaces of the second set defining respective cutting edges along each line of intersection of the first distinct set of at least three non-linear intersection surfaces with the second distinct set of at least three non-linear intersecting surfaces.

As stated above, Smith fails to show or suggest, *inter alia*, respective cutting edges along each line of intersection of the first distinct set of intersecting surfaces with the second distinct set of intersecting surfaces as required by independent claim 23.

Silverman fails to cure the deficiencies of Smith as Silverman teaches away from having cutting edges on the portion of the needle proximal to the needle point and thus, the references cannot be combined. Moreover, the Examiner's rationale for combining the references is faulty. The Examiner asserts in the Final Office Action that:

> The device of Smith is not explicitly disclosed with the first and second sets having at least three surfaces. Silverman et al teach a needle having at least three surfaces (see figures 1A-1C). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Smith to have the first and second sets having at least three surfaces in view of Silverman et al in order to provide more cutting edges for more efficient cutting and penetration of tissue.

As stated above, Silverman discloses the conical point portion of the needle having a round or substantially rounded cross section without any sharp, angular, or square edges. How then, would it be obvious to modify the device of Smith in view of Silverman to have more cutting edges if Silverman teaches away from having edges on the portion of the needle proximal to the needle point? It is only with impermissible hindsight that the Examiner has gleaned information from Appellant's disclosure, and not the references cited, to form this obviousness rejection.

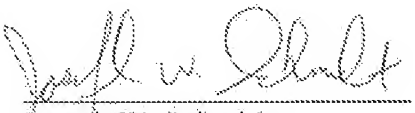
Cottrill is relied upon for the recitation of concave surfaces in a needle and fails to cure the deficiencies of Smith and Silverman.

In view of the foregoing, Appellant respectfully requests that the rejection of claim 23, and claims 13, 14, 16-19, and 23-25 which depend therefrom, under 35 U.S.C. §103(a) over Smith in view of Silverman and Cottrill be reversed.

C. **Conclusion**

The Examiner has not establish the essential elements for a *prima facie* case of obviousness as the combination of references is improper and fails to disclose the various elements, does not suggest the claimed combination, and the Examiner has not presented a convincing line of reasoning for combining the references. In view of the foregoing it is respectfully submitted that the rejections under 35 U.S.C. §103(a) of claims 2, 3, 10, 11, 13, 14, 16-20, and 22-25 should be reversed.

Respectfully submitted,



Joseph W. Schmidt
Reg. No.: 36,920
Attorney for Applicant(s)

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road, Suite 420
Melville, New York 11747
Telephone: (631) 501-5700
Facsimile: (631) 501-3526

VIII. CLAIMS APPENDIX

1. (Canceled)

2. The surgical needle according to claim 20 wherein the first set of the four concave surfaces of the needle end are obliquely arranged relative to the longitudinal axis at a first angle.

3. The surgical needle according to claim 2 wherein the second set of the four concave surfaces of the needle tip are obliquely arranged relative to the longitudinal axis at a second angle greater than the first angle.

4. – 9. (Canceled)

10. The surgical needle according to claim 20 wherein the main shaft is curved along the longitudinal axis of the needle body.

11. The surgical needle according to claim 20 wherein the main shaft includes means for attaching a suture.

12. (Canceled)

13. The surgical needle according to claim 23 wherein the at least three non-

linear surfaces of the first set define cutting edges along lines of intersection of adjacent surfaces thereof.

14. The surgical needle according to claim 13 wherein the at least three non-linear surfaces of the second set define cutting edges along lines of intersection of adjacent surfaces thereof.

15. (Canceled)

16. The surgical needle according to claim 14 wherein the first set includes four non-linear surfaces.

17. The surgical needle according to claim 16 wherein the second set includes four non-linear surfaces.

18. The surgical needle according to claim 17 wherein the four non-linear surfaces of each of the first set and the second set are generally concave.

19. The surgical needle according to claim 23 wherein the at least three non-linear surfaces of each of the first set and the second set are generally concave.

20. A surgical needle, which comprises:

an elongated needle body defining a longitudinal axis and proximal and distal

ends, the elongated needle body including a main shaft adjacent the proximal end, a needle end adjacent the main shaft defining a generally diamond-shape in cross-section along an axis transverse to the longitudinal axis and a maximum cross-sectional dimension greater than a corresponding maximum cross-sectional dimension of the main shaft, and a needle tip extending distally from the needle end defining a generally diamond-shape in cross-section along an axis transverse to the longitudinal axis and having an extreme needle point, the needle end including a first distinct set of four generally concave intersecting surfaces extending between the needle tip and the main shaft, the needle tip including a second distinct set of four generally concave intersecting surfaces extending between the needle point and the needle end to intersect the first set of concave surfaces of the needle end, and cutting edges disposed along each respective line of intersection of the first set of four surfaces of the needle end with the second set of four surfaces of the needle tip.

21. (Canceled)

22. The surgical needle of claim 20 wherein the concave surfaces of the first set are symmetrically arranged about the longitudinal axis and wherein the concave surfaces of the second set are symmetrically arranged about the longitudinal axis.

23. A surgical needle, which comprises:

an elongated needle body defining a longitudinal axis and proximal and distal ends, the elongated needle body including a main shaft adjacent the proximal end, a first distinct set of at least three non-linear intersecting surfaces distally extending from the main shaft and a

second distinct set of at least three non-linear intersecting surfaces contiguous with the first set of at least three non-linear intersecting surfaces and extending distally therefrom to an extreme distal needle point, the at least three non-linear intersecting surfaces of the first set and the at least three non-linear intersecting surfaces of the second set defining respective cutting edges along each line of intersection of the first distinct set of at least three non-linear intersection surfaces with the second distinct set of at least three non-linear intersecting surfaces.

24. The surgical needle of claim 23 wherein the at least three non-linear intersecting surfaces of the first set are symmetrically arranged about the longitudinal axis and wherein the at least three non-linear intersecting surfaces of the second set are symmetrically arranged about the longitudinal axis.

25. The surgical needle of claim 18 wherein the four non-linear surfaces of the first set are symmetrically arranged about the longitudinal axis and wherein the four non-linear surfaces of the second set are symmetrically arranged about the longitudinal axis.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None